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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,887	04/06/2001	Charles D. Claude	ACSC-60087	5563

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EXAMINER

AHMED, SHEEBA

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,887

Applicant(s)

CLAUDE ET AL.

Examiner

Sheeba Ahmed

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-36 and 38-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36 and 38-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Amendments to claims 33, 34, 36, 38, and 41 have been entered in the above-identified application. New claims 43-48 have been added. **Claims 33-36 and 38-48 are now pending.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 33-36 and 38-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 33 has been amended to recite that the balloon catheter comprises "a polymeric first layer having a deposited plasma polymerized acrylate or fragmented acrylate polymer film". There is no explicit or implicit support for a "fragmented acrylate polymer film" in the original disclosure. The Applicants fail to point to any support for such an amendment and the Examiner was unable to find any support. Applicants are required to cancel any new matter in response to this Office

Art Unit: 1773

Action and are reminded that any previously applied art rejections may be reinstated upon cancellation of the new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (US 6,048,620).

Zhong discloses balloon catheters for angioplasty (Column 1, lines 25-26) wherein at least the balloon part is provided with a coating comprising a polymer having organic acid functional groups and a crosslinking agent having functional groups capable of reacting with organic acid groups wherein the coating is applied, dried and then further coated with a hydrophilic polymer having organic acid functional groups such that the hydrophilic polymer becomes bonded to the polymer of the first coating composition through the crosslinking agent (***the balloon part disclosed by Zhong corresponds to the second layer of the claimed invention, the first coating disclosed by Zhong corresponds to the covalently bonded functionality of the claimed invention and the second coating disclosed by Zhong corresponds to the first coating of the claimed invention***) (Column 3, lines 15-30). Examples of organic acid groups include carboxylic acid groups (Column 4, lines 53-56). Examples of the

Art Unit: 1773

first coating composition include acrylic copolymer dispersions (***thus meeting the limitations of claims 36 and 37***) (Column 5, lines 30-33). However, Zhong teaches that the materials used to make a balloon catheter include polytetrafluoroethylene, nylons, PE, PP, PVC and other resins (Column 8, lines 44-55).

Zhong et al. does not teach that their first coating has a thickness of about 10 to 150 nanometers.

However, it would have been obvious to optimize the thickness of the first coating as taught by Zhong given that the coating thickness of a coating can be controlled to obtain specific properties and it is desirable to obtain a thin coating thickness for a bonding layer. Furthermore, the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see MPEP 2113. In this case, the product (i.e., the balloon catheter) is obvious despite the process limitation of plasma polymerizing the functionalized layer.

Response to Arguments

4. Applicant's arguments with respect to claims 33-36 and 38-41 have been considered but are moot in view of the new ground(s) of rejection.

With regards to the rejection of claim 42, the Applicants argue that the plasma polymerization process provides the energy required to produce the polymerized acrylic

Art Unit: 1773

acid film which covalently bonds to the substrate/first layer without requiring a polyfunctional crosslinking agent as used by Zhong. First, the Examiner would like to remind the Applicants that the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see MPEP 2113. In this case, the product (i.e., the balloon catheter or medical device) is obvious despite the process limitation of plasma polymerizing the functionalized layer. Second, the language of the instant claims does not preclude the use of a polyfunctional crosslinking agent.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


Art Unit: 1773

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheeba Ahmed whose telephone number is (571)272-1504. The examiner can normally be reached on Mondays and Thursdays from 9:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on (571)272-1535. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sheeba Ahmed
Art Unit 1773
February 22, 2005